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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,770	07/02/2001	Edward M. Lichten	20013810-0003	4869

7590 12/09/2003

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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 12/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/898,770

Applicant(s)

LICHTEN, EDWARD M.

Examiner

Dr. Kailash C. Srivastava

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) 1-35, 40, 44-45, 49 and 51-65 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-39, 41-43, 46-48 and 50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Applicant's amendment filed 09/15/2003 is acknowledged and entered. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.
2. The Art Unit location of your application in the USPTO is 1651, not 4869 as noted in the above-cited amendment. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1651.
3. Claims 1-65 are pending.
4. Examiner herewith clarifies that Claims 1-35, 40, 44-45, 49 and 51-65 have previously been withdrawn from further consideration as being directed to a without traverse non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Examiner suggests that the non-elected claims cited *supra* be canceled in response to this Office action to expedite prosecution.
5. Claims 36-39, 41-43, 46-48 and 50 are examined on merits.

### ***Claim Rejections - 35 U.S.C. § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. § 112:  

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*
7. Claims 36-39, 41-43, 47-48 and 50 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with those claims. The claims are directed to a method to restore hormonal balance in a mammal, wherein said method comprises administering

to said mammal a “hormone-disorder effective amount” of a therapeutic agent. Said therapeutic agent comprises insulin (Applicant has elected insulin as the therapeutic agent, see response to election/restriction requirement filed 01/22/2003 as paper number 3).

From the record of the present written disclosure, the specification provides support to determine factors P and Q (e.g., Page 16, Lines 4-21) for human male and female, respectively and steps claimed in Claims 36 (i) to 36 (iv) for human female (i.e., Example 6). The specification does not reasonably provide a method to restore hormonal balance; definitions for, or methods to determine the “prescription plan” (e.g., Specification Page 12, Lines 3-6), “Free Insulin Testosterone Index (Page 18, Lines 14-27; Page 35, Line 1), and factors F, P and Q in any or all mammals. Furthermore, in examples 1-5, applicant only demonstrates administering certain hormones to some individuals and effect of said treatment, not all of the steps (i) to (iv) in claim 36. Thus, the claimed invention in its entire scope has not been sufficiently exemplified in the specification. Furthermore, applicant has also not clarified why calculation for factor F is based on the data for estrogen/ testosterone levels found in a 18 year old human female or male (Page 16, Line 29 to Page 17, Line 20)?

An ordinary artisan would not be able to practice the invention because an undue experimentation will be required to determine Free Insulin Testosterone Index and Factors F, P, and Q for any or all mammals, including humans recited in said claims. Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples (because Specification gives examples on administration of a therapeutic amount and effects of said treatment without demonstrating levels of different hormones claimed in Claim 36, determining F factor for a prescription plan or a prescription plan or how the therapeutic dose was determined

for those individuals), nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

8. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.*

9. Claims 36-39, 41-43, 46-48 and 50 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 36(iii) is rendered vague and indefinite because the “F factor” recited in said claim is not defined. Applicant is requested to define or clarify the phrase “F factor”.
- Claim 36(iv) is rendered vague and indefinite because the phrases “Free Insulin Testosterone Index” and “Prescription Plan” recited in said claim are not defined. An artisan will not be able to determine the “Free Insulin Testosterone index” or a “Prescription Plan” from the claim language. Applicant is requested to define or clarify the phrases “Free Insulin Testosterone index” and “Prescription Plan”.
- In Claim 48, the phrase “wherein the human is female” lacks sufficient antecedent basis because Claim 48 depends from Claim 36, which recites, “a method for restoring hormone balance in a mammal”.
- In Claim 50, the phrase “wherein the human is male” lacks sufficient antecedent basis because Claim 50 depends from Claim 36, which recites, “a method for restoring hormone balance in a mammal”.

All other claims depend directly from the rejected claim 36 and are, therefore, also rejected under 35 U.S.C. §112, second paragraph for the reasons set forth above.

10. Amended Claim 36 is free of prior art. Since Claims 37-39, 41-43, 46-48 and 50 depend from Claim 36, they are also free of prior art cited in Office Action mailed 04/08/2003.


### CONCLUSION

11. No Claims are allowed.

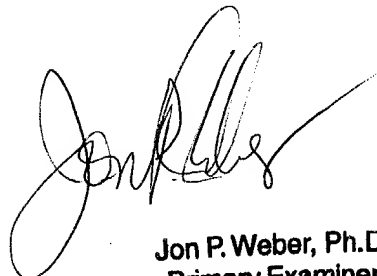
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703)-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

 Kailash C. Srivastava, Ph.D.  
Patent Examiner  
Art Unit 1651  
(703) 605-1196

December 4, 2003

  
Jon P. Weber, Ph.D.  
Primary Examiner